



INFECTODELL®

Treatment of molluscum contagiosum





What is molluscum contagiosum?

- Viral infection caused by the *molluscum contagiosum virus* (MCV), a *poxvirus*
 - Small umbilicated papules
 - Diameter: 2-5 mm
 - Skin colored or reddish, rarely whitish
 - Often grouped
-
- Important differences to common warts (*Verruca vulgaris*)
 - Smooth and pearly/shiny surface
 - Dome-shaped with a little crater in some cases
 - a whitish compound (infectious) leaks from the papules under pressure





Occurrence of molluscum contagiosum

Body:

- Stem, extremity, face, anogenital area
- rarely: hands and feet
- Usually less than 20 papules
- Very rarely cases with more than 100 papules

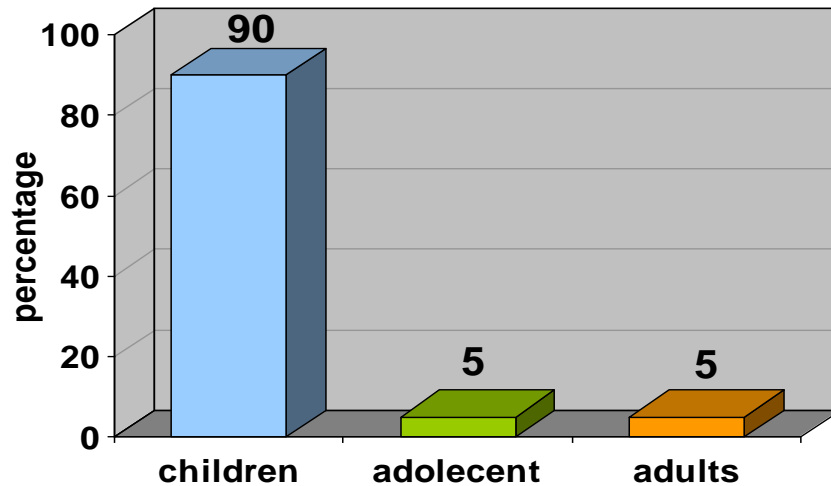
Geographic distribution :

- Worldwide from the tropics to Alaska
- Incidence is higher in warm and moist areas



Who is concerned?

Distribution of MCV infections



Warm climate: Peak between 1-6 years of age

Cold climate: Peak between 6-10 years of age

Adults: dermatological and autoimmune disorders

Mainly affected: **patients with a history of atopy** (>100 papules)



Incidence/prevalence

England/Scotland:

2,4 new infections per 1 000 inhabitants and year

Germany:

- approx. 190 000 cases/ year
- 2-8% in school-aged children (Ucmak *et al.*, 2014)

Seroprevalence (Sherwani *et al.* 2014)

- Germany (children and adults 0-40 years): 14.8%
 - Children < 1 year: 4.5%
 - **Children 2 – 10 years: 25% approx. 150 000 cases** (births 2012: 673 500)
 - Population 11-40 years: 12.5%
- England: 30%
- Switzerland: 4.9%

How is MCV transmitted?

- Transmission from human to human ...
 - Small epithelial defects (scratches)
 - Smear infection (auto- and heteroinoculation)



- Rarely through commonly used clothes or towels
 - Swimming pools
 - Kindergarten
- Incubation time: 2 weeks until 8 months



Spontaneous resolve?

- **Spontaneous resolving process**
 - 2-3 months (single papules)
 - 6-9 months (all papules)
 - 1-5 years (patients with atopic history)
- **Spontaneous resolve: why should MCV be treated?**
 - especially children experience social stigmatization and embarrassment
 - cosmetic issues
 - very high contagiousness
 - Treatment avoids spreading and transmission



! Treatment should be inexpensive, simple, effective and should avoid relapse



Invasive therapy

- Curettage
(in combination with local anesthetics)
 - Forceps/ needle
 - Cryotherapy
 - Squeezing
- invasive
 - painful
 - server side effects can occur (scars)
 - high risk of relapse
 - time-consuming
 - every single blister has to be removed

Aggressive treatment is no option !



Non-invasive treatment (keratolytic substances)

- Liquid nitrogen
- Salicylic acid
- Fluorouracil
- Imiquimod
- Silver nitrate
- Phenol
- Chloroacetic acid
- most of these substances act via keratolysis and are applicable for the use of common warts
- very corrosive

Patients need an effective, inexpensive and simple treatment!



The solution for Molluscum contagiosum 5% potassiumhydroxid

- Simple
- Efficient
- Reliable





- medical device class 1, CE-certified for Europe
- 1ml contains 50mg potassiumhydroxid (5 % KOH)
- indicated for the topical treatment of MCV
- Recommended after two years of life
- USP: InfectoDell is the only compound for the treatment of MC



InfectoDell may **not** be used:

- In areas close to eyes
- On inflammatory areas, such as inflamed papules
- On mucosa (mouth and genital area)
- For the treatment of common warts or clavus
- For immunocompromised patients
- In case of keloid
- **For children younger than two years of life**





InfectoDell mode of action

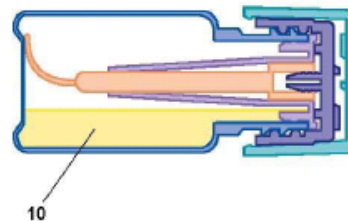
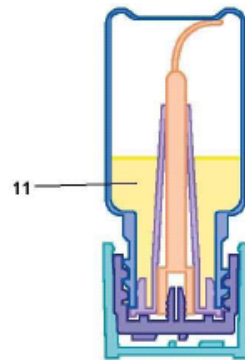
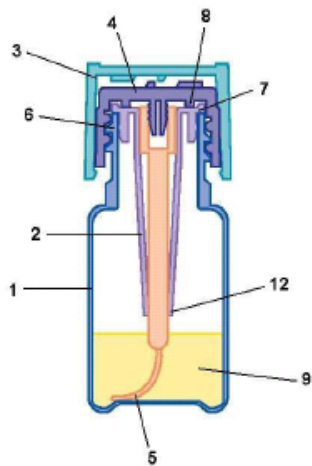
- Application 2x daily
- Keratolysis of epidermis cells (proteolysis)
- Alkaline hydrolysis of membrane lipids (protecting cover)
- Breakdown of viral proteins
- Immune system recognizes MCV
- Inflammation is induced (after approx. 4-6 days)
- Relief after 1-5 weeks („drop off of the papules“)



Product safety

INFECTODELL®

- In 2013 we improved the safety of our product to minimize the risk of alkaline burn
- New patented container and packaging
 - avoids leaking
 - guarantees to remove only the needed volume for treatment





Clinical evaluation

- Proof of effectiveness
 - 1 Study using 2,5% KOH (Ucmak *et al.*, 2014)
 - 2 Studies using 5% KOH (Romiti *et al.*, 2000; Jansen *et al.*, 2007, Ucmak *et al.*, 2014)
 - 2 Studies using 10% KOH (Romiti *et al.*, 1999; Short *et al.*, 2006; Metkar *et al.*, 2008)
 - 1 Study using 15% KOH (Hinostroza-Da-Conceicao und Beirana-Palencia, 2004)
 - 1 Study using 20% KOH (Mahajan *et al.*, 2003)
- 80% of treated patients are free of MC after 4 weeks (Jansen *et al.*, 2007)
- No relapse after 2-8 months
- No scars
- No severe side effects (light stinging for 1-2min after application of 5 or 10% KOH)



Advantages of InfectoDell

- Simple application
- Can be applied by parents or patient at home
- Non invasive treatment, no scars
- Does not hurt
- **high compliance**
- Plenty of literature confirms effectiveness
- No relapse due to immunological reaction
- Very safe



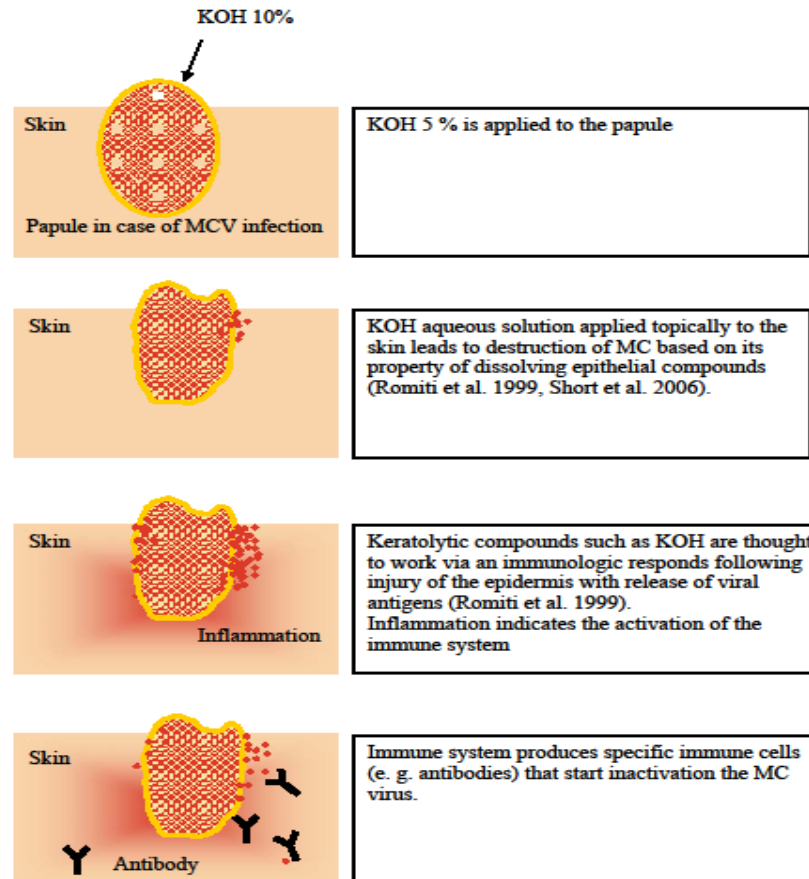
FAQ

- **Do I need to apply on each papules?**
 - Yes, Infectodell should be applied on each papules.
- **How do antibodies attack the MC viruses?**
 - First Infectodell destroys the viral cells. Due to the contact with the viral material the immune system starts producing antibodies that detect surface on the viral envelope. Viral cells that are tagged with the antibody, can be cleared by immune cells subsequently.
- **Can MC relapse after the Infectodell treatment, ever in human life?**
 - Yes, it is possible. Specific antibodies do not last a lifetime.

Mode of action

Mode of action of potassium hydroxide (KOH) on *Mulloscum contagiosum*

Please note that the schematic mode of action shown below is presented in a very simplified way. Scientifically there are more details that have to be taken into account. The drawings can therefore no be considered as scientifically correct.





Market is difficult to define

- InfectoDell is the only compound for the treatment of MC
- Most important “competitor”:
 - curettage
- Other drugs are indicated for the treatment of common warts
 - keratolytic substances



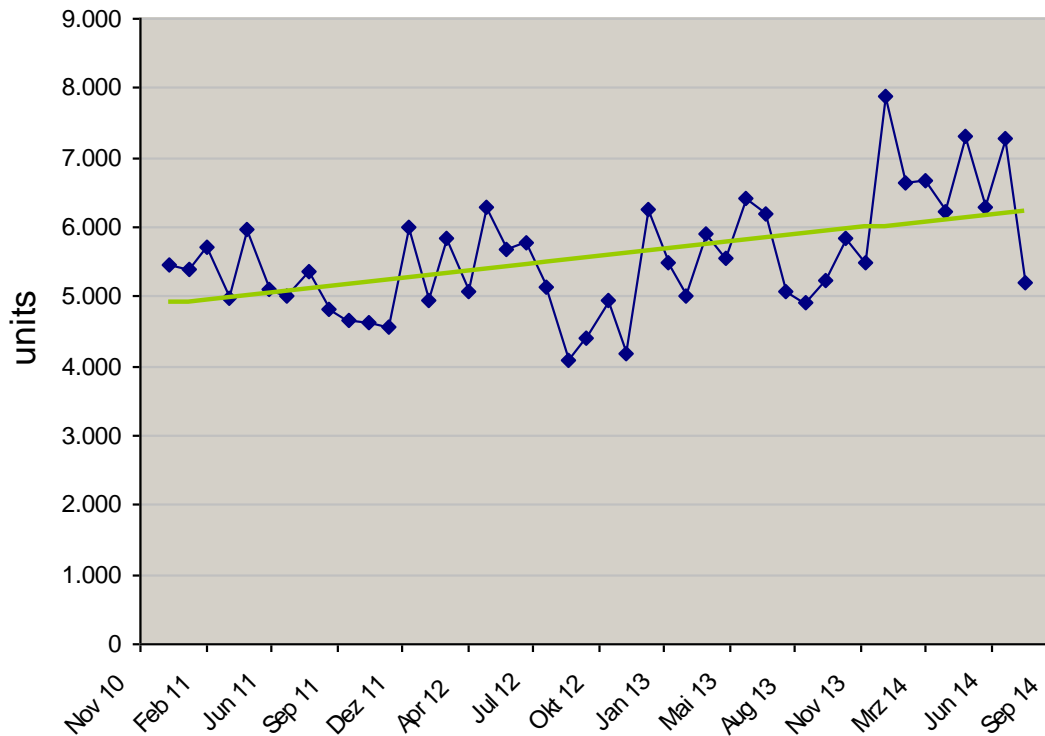
Product performance in Germany

InfectoPharm launched the product in November 2006

Current InfectoPharm market share: approx. 40-50%

Population: 80 M

Sales 2011 - 2014



Sales are still increasing!

2015 forecast:
80 000 pack./year

Potential:
150 000 pack./year



Literature

- Romiti *et al.*, 2000
- Jansen *et al.*, 2007
- Romiti *et al.*, 1999
- Short *et al.*, 2006
- Metkar *et al.*, 2008
- Hinostroza-Da-Conceicao and Beirana-Palencia, 2004
- Mahajan *et al.*, 2003
- Ucmak *et al.*, 2014



Features

- High compliance
- Minimal side effects
- No bleeding on use
- No local anaesthetic required
- Efficiency proved by clinical trial

“Topical potassium hydroxide for the treatment of Molluscum contagiosum saves children from the more aggressive physical forms of treatment”



Thank you!

INFECTODELL[®]

- Simple
- Efficient
- Reliable

